

# 3

Animal Product  
Manual

## Reference

### *Live Animals and Related Material*

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#### Introduction

The *Live Animals and Related Material* section covers importations of living organisms and related material for which DHS-CBP has approval to take regulatory action. Examples include embryos, ova, and semen; organisms and vectors, including microorganisms (viruses, bacteria) imported for research purposes; antisera; diagnostic reagents; monoclonal antibodies; test kits; and antivenin.

**Not** covered in this section are the following live animal importations:

- ◆ Blood or a derivative of blood; regulate these by-products under ***Blood and Related By-Products***


- ◆ Eggs for hatching, including commercial importations of uncooked baluts. Contact the nearest VS office for further action. Consider eggs being imported for research as embryos; see [Table 3-8-20](#)
- ◆ Extracts or derivatives of animal organs or glands; regulate these by-products under [Organs](#)
- ◆ Human pharmaceuticals and human vaccines in final dosage form; see [Human Pharmaceuticals and Human Vaccines](#) on [page 3-15-12](#)
- ◆ Importations of live animals, except for laboratory animals (see [Animal Tissue](#) on [page 3-8-8](#)). Consult with local VS for notification and procedures for any live animal import **other than** those handled by the U.S. Public Health Service (PHS)
- ◆ Live animals found while clearing aircraft or vessels; see [Safeguarding Live Animals](#) on [page 2-4-32](#)
- ◆ Nonhuman primates, dogs and cats; see PHS, and also refer nonhuman primates to FWS. The Centers for Disease Control and Prevention (CDC) has jurisdiction over the importation of dogs, cats, and nonhuman primates. The importer should contact the CDC for import restrictions (phone 404/639-3311)
- ◆ Pet birds in passenger baggage and aboard vessels or yachts and pleasure vessels; see [Handling Pet Birds](#) on [page 2-4-20](#)
- ◆ Used semen and embryo containers; see [Empty Semen and Embryo Containers](#) on [page 2-2-12](#) for action to take
- ◆ Veterinary biologics such as bacterins, vaccines, toxins, toxoids, and test kits for the diagnosis of animal diseases. These animal products are authorized entry under a veterinary biological product permit issued by VS, Center for Veterinary Biologics; see [Requests for VS Permits](#) on [page 2-4-27](#)

When a VS permit authorizes entry of live animals, match the following information on the shipping documents with that on the permit:

- ◆ Current date
- ◆ Description of the material
- ◆ Shipper
- ◆ Consignee
- ◆ Conditions spelled out on the permit

Follow [Table 3-8-1](#) as you match the permit with the shipping documents.

**TABLE 3-8-1 Validate Importation Authorized Entry by a VS Permit**

If the shipping documents:	And the:	Then:
Match the permit		RELEASE or CONTROL as specified on the permit
<b>Do not</b> match the permit	Permit has expired	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. HAVE the consignee contact VS, TTSPS, IEAS, or CVB (see <a href="#">page 2-4-28</a>)</li> <li>3. SAFEGUARD the importation until you hear from VS, TTSPS</li> </ol>
	Discrepancy is <b>other than</b> an expired permit	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a>)</li> </ol>

## Locator






When a VS permit **does not** accompany an importation of live animals, use [Table 3-8-2](#) to determine the appropriate regulatory action to take.

**TABLE 3-8-2 Where to Find Regulatory Action on Live Animals and Related Material Not Authorized By a VS Permit**

If the importation is:	Then:
Amphibians	Go to <a href="#">Table 3-8-11</a>
Aquatic animals (including fish, sharks, shellfish, and whales)	
Animal tissue	Go to <a href="#">Table 3-8-6</a>
Cat (feline) materials	Go to <a href="#">Table 3-8-10</a>
Dog (canine) materials	
Earthworms	GO to <a href="#">Table 3-8-3</a>
Human materials	Go to <a href="#">Table 3-8-8</a>
Laboratory mammals and their related materials	GO to <a href="#">Table 3-8-7</a>
Microorganisms (bacteria, viruses, fungi)	GO to <a href="#">Table 3-8-4</a>
Organisms and vectors	GO to <a href="#">Table 3-8-12</a>
Nonhuman primate materials	GO to <a href="#">Table 3-8-9</a>
Ova and embryos	GO to <a href="#">Table 3-8-20</a>
Reptiles	Go to <a href="#">Table 3-8-11</a>
Semen from equine	GO to <a href="#">Table 3-8-18</a>
Semen from <b>other than</b> equine	GO to <a href="#">Table 3-8-19</a>
<b>Used</b> embryo, ova, or semen containers	GO to <a href="#">Empty Semen and Embryo Containers</a> on <a href="#">page 2-2-12</a>
<b>Other than</b> described above	CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

## Earthworms

TABLE 3-8-3 Earthworms


If:	And the country of origin is:	And the earthworms are:	And from:	And:	Then:
<ul style="list-style-type: none"> <li>◆ Live earthworms</li> <li>◆ Freeze-dried earthworms</li> <li>◆ Any other form of earthworms</li> </ul>	Canada	In soil	<ul style="list-style-type: none"> <li>◆ Newfoundland</li> <li>◆ Portion of the Municipality of Central Saanich on Vancouver Island in the Province of British Columbia east of West Saanich Road</li> </ul>		REFUSE ENTRY
			Part of Canada <b>other than</b> that described in the cell above		RELEASE <sup>1</sup>
		Not in soil			
	Other than Canada			Is accompanied by PPQ Form 526, Permit to Move Live Plant Pests <sup>2</sup>	RELEASE <sup>1</sup> or CONTROL as specified on the permit
				Lacks the permit	REFUSE ENTRY

1 Because live earthworms are perishable, expedite shipments that you are authorized to release.

2 Since earthworms may harbor plant pathogens in their guts, earthworms are regulated by 7CFR 330.200.

## Microorganisms (Bacteria, Viruses, Fungi)

TABLE 3-8-4 Microorganisms

If:	And:	Then:
Recombinant microorganism		GO to <a href="#">Table 3-8-5</a>
Nonrecombinant microorganism <sup>1</sup>	Is accompanied by shipper or producer's declaration <sup>2</sup>	RELEASE
	<b>Lacks</b> the shipper or producer's declaration or statements <sup>2</sup>	<b>DO NOT RELEASE</b> the HOLD until the importer provides the required documentation

- 1 Examples of nonrecombinant, nonpathogenic microorganisms are as follows: *Lactobacillus* (used to manufacture yogurt); *Micrococcus* (skin bacterium); *Penicillium* (used to produce penicillin, an antibiotic); and *Serratia* (soil microbe).

Examples of microorganisms requiring a permit to authorize entry are as follows: *Hemophilus influenzae*, *Actinobacillus equuli*, *Actinomyces bovis*, *Streptococcus bovis*, *Rhodococcus equi*, *Helicobacter pylori*, *Lawsonia intracellularis*, *Clostridium perfringens*, *Pasteurella multocida*, Bluetongue virus, Vesicular stomatitis virus, porcine parvovirus, and epizootic hemorrhagic disease virus.

- 2 An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:
- ◆ Genus and species of the microorganism
  - ◆ Microorganism is **not** considered to be pathogenic to livestock or poultry

### Recombinant Microorganisms

Recombinant microorganisms can be bacteria, viruses, or yeast. Recombinant technology involves the transfer of genes from one organism into another organism. Examples of transference include the following:

- ◆ Transferring insect or herbicide resistance to plants
- ◆ Transferring normal human genes to replace defective ones
- ◆ Transferring genes which manufacture hormones or enzymes to those that **do not**

The most common recombinant microorganisms are as follows:

- ◆ Bacteria, *Escherichia coli* and *Bacillus subtilis*
- ◆ Yeasts, *Streptomyces* and *Saccharomyces*
- ◆ Virus, *Vaccinia*

TABLE 3-8-5 Recombinant Microorganisms

If:	And the microorganism:	And the importation:	Then:
Recombinant microorganisms	Contains animal-derived additive or stabilizer, e.g., albumin	Is accompanied by shipper or producer's declaration <sup>1</sup>	RELEASE
		<b>Lacks</b> the shipper/producer's declaration <sup>1</sup>	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required documentation
	<b>Does not</b> contain animal-derived additive or stabilizer	Is accompanied by shipper or producer's declaration <sup>2</sup>	RELEASE
		<b>Lacks</b> the shipper/producer's declaration	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required documentation

- 1 An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:
  - ◆ Genus and species of the microorganism
  - ◆ Additive or stabilizer
  - ◆ The material is produced by recombinant microbial expression (vector **must not** be considered pathogenic for livestock or avian species)
  - ◆ The product will be used **only** in vitro
  - ◆ The microorganism **does not** contain genes or express antigens of livestock or poultry diseases
- 2 An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:
  - ◆ Genus and species of the microorganism
  - ◆ Microorganism **does not** contain an animal-derived additive or stabilizer
  - ◆ The material is produced by recombinant microbial express (vector **must not** be considered pathogenic for livestock or avian species)
  - ◆ The microorganism **does not** contain genes or express antigens of livestock or poultry disease agents

## Animal Tissue

**TABLE 3-8-6 Action to Take on Animal Tissue**

If the tissue originated from:	Then:
Amphibians, aquatic species, or reptiles	GO to <a href="#">Table 3-8-11</a>
Canines (dogs)	GO to <a href="#">Table 3-8-10</a>
Felines (cats)	
Humans	GO to <a href="#">Table 3-8-8</a>
Laboratory animals (including gerbils, guinea pigs, hamsters, mice, rabbits, or rats)	GO to <a href="#">Table 3-8-7</a>
Livestock (horses, ruminants, swine or avian species (birds and poultry))	<ol style="list-style-type: none"><li>1. <b>DO NOT</b> RELEASE the HOLD</li><li>2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing the entry</li><li>3. PROVIDE the importer with the appropriate options, including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-27</a>)</li></ol>
Nonhuman primates	GO to <a href="#">Table 3-8-9</a>



## Laboratory Mammals and Various Vertebrates and Invertebrates and Their Associated Materials



This section **does not** include cats, dogs, and nonhuman primates.

For the purposes of this section, laboratory mammals (and their products) include gerbils, guinea pigs, hamsters, mice, rabbits, rats, transgenic rabbits, transgenic rats, and transgenic/knockout mice; see [Table 3-8-7](#) on [page 3-8-10](#).

### Centers for Disease Control and Prevention (CDC) Regulations Overlap

The Centers for Disease Control and Prevention (CDC) regulates the importation of cats, dogs, live laboratory animals, and nonhuman primates.



If the cages containing the animals also contain fruits or vegetables (used as a source for water), then have the importer or the importer's agent remove any prohibited material prior to being released to a consignee.

## Live Laboratory Mammals and Their Associated Materials

**TABLE 3-8-7 Live Laboratory Mammals and Their Associated Materials**

If the importation is:	And is:	Then:
Live laboratory mammals for research purposes	<ul style="list-style-type: none"> <li>◆ Gerbils</li> <li>◆ Guinea pigs</li> <li>◆ Hamsters</li> <li>◆ Mice</li> <li>◆ Rabbits</li> <li>◆ Rats</li> <li>◆ Transgenic rabbits</li> <li>◆ Transgenic rats</li> <li>◆ Transgenic/knockout mice</li> </ul>	CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items
	<b>Other than</b> one listed in the cells above	CONTACT and REFER to the Centers for Disease Control and Prevention which has jurisdiction over these items at 404/718-2077
Live laboratory mammal materials for research purposes	<ul style="list-style-type: none"> <li>◆ Blood fractions<sup>1</sup></li> <li>◆ DNA</li> <li>◆ Enzymes</li> <li>◆ Extracts</li> <li>◆ Feces</li> <li>◆ Fluids</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ RNA</li> <li>◆ Semen</li> <li>◆ Tissue</li> <li>◆ Urine</li> </ul>	CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items
	<b>Other than</b> one listed in the cells above	CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items

<sup>1</sup> Blood fractions include albumin, antibodies, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.

## Human Materials

**TABLE 3-8-8 Human Materials**

If the imported material was collected from:	And is:	Then:
Humans	<ul style="list-style-type: none"> <li>◆ Blood fractions<sup>1</sup></li> <li>◆ DNA</li> <li>◆ Enzymes</li> <li>◆ Extracts</li> <li>◆ Feces</li> <li>◆ Fluids</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ RNA</li> <li>◆ Semen</li> <li>◆ Tissue</li> <li>◆ Urine</li> </ul>	CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items
	<b>Other than</b> one listed in the cells above	CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items

<sup>1</sup> Blood fractions include albumin, antibodies, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.

## Nonhuman Primate Materials

**TABLE 3-8-9 Nonhuman Primate Materials**

If the imported material was collected from:	And is:	Then:
Nonhuman primates	<ul style="list-style-type: none"> <li>◆ Blood fractions<sup>1</sup></li> <li>◆ DNA</li> <li>◆ Enzymes</li> <li>◆ Extracts</li> <li>◆ Feces</li> <li>◆ Fluids</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ RNA</li> <li>◆ Semen</li> <li>◆ Tissue</li> <li>◆ Urine</li> </ul>	CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items
	<b>Other than</b> one listed in the cells above	CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items

<sup>1</sup> Blood fractions include albumin, antibodies, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.

## Canine (Dog) and Feline (Cat) Materials


**TABLE 3-8-10 Canine (Dog) and Feline (Cat) Materials**

If the imported material was collected from:	And is:	Then:
<ul style="list-style-type: none"> <li>◆ Canines (dogs)</li> <li>◆ Felines (cats)</li> </ul>	<ul style="list-style-type: none"> <li>◆ Blood fractions<sup>1</sup></li> <li>◆ DNA</li> <li>◆ Enzymes</li> <li>◆ Extracts</li> <li>◆ Feces</li> <li>◆ Fluids</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ RNA</li> <li>◆ Semen<sup>2</sup></li> <li>◆ Serum</li> <li>◆ Tissue</li> <li>◆ Urine</li> <li>◆ Venom</li> </ul>	<ol style="list-style-type: none"> <li>1. CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items</li> <li>2. If you have a question regarding live canine (dog) or feline (cat) animals, CALL 404/639-3441</li> </ol>
	Other than one listed in the cells above	<ol style="list-style-type: none"> <li>1. CONTACT and REFER to the Centers for Disease Control and Prevention, 404/718-2077, which has jurisdiction over these items</li> <li>2. If you have a question regarding live canine (dog) or feline (cat) animals, CALL 404/639-3441</li> </ol>

- 1 Blood fractions include albumin, antibodies, antiserum, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.
- 2 If dog semen is to be used for reproductive purposes and **not** research, then the semen is unrestricted as long as the species is confirmed.

## Amphibian, Aquatic Animal, and Reptile Materials

**TABLE 3-8-11 Materials Derived from Amphibians, Aquatic Animals, and Reptiles**

If the imported material is from:	And is:	And:	Then:
<ul style="list-style-type: none"> <li>◆ Amphibians</li> <li>◆ Aquatic animals (including fish, sharks, shellfish, whales)</li> <li>◆ Reptiles</li> </ul>	<ul style="list-style-type: none"> <li>◆ Blood fractions<sup>1</sup></li> <li>◆ DNA</li> <li>◆ Enzymes</li> <li>◆ Extracts</li> <li>◆ Feces</li> <li>◆ Fluids</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ RNA</li> <li>◆ Semen</li> <li>◆ Tissue</li> <li>◆ Urine</li> </ul>	Is accompanied by the shipper or producer's declaration <sup>2</sup>	RELEASE
		Lacks the shipper/producer's declaration or statements <sup>2</sup>	<b>DO NOT RELEASE</b> the HOLD until the producer or shipper provides the required statement
Other than one listed above			1. <b>DO NOT RELEASE</b> the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

1 Blood fractions include albumin, antibodies, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.

2 An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:

- ◆ Identification of the material and species of origin
- ◆ Material **does not** contain any avian, equine, ruminant, or swine species products (such as in transport media or stabilizers)

## List of Laboratories Working with Exotic Viruses, Including FMD

Country	Laboratory
Australia	CSIRO, Division of Animal Health Geelong, Victoria
Brazil	Centro Panamericano de Fiebre Aftosa Rio de Janeiro
Botswana	Botswana Vaccine Institute Department of Animal Health and Production Gaborone
Canada	Animal Disease Research Institute, Virology Section Nepean, Ontario
France	CNEVA Lyon, Laboratoire de pathologie bovine Lyon, Cedex CIRAD, Department d'élevage et de médecine vétérinaire
Germany	Hannover Veterinary School, Institute of Virology Bunteweg 17, Hanannover Institut für Geflügelkrankheiten der Justus-Liebig Giessen
Iran	Razi Vaccine and Serum Institute, Tehran
Italy	Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia "B Ubertini" Brescia National Centre for Exotic Diseases Teramo
Japan	National Institute for Animal Health Ibaraki
Kenya	Organisation for African Unity/ Interafrican Bureau for Animal Resources, Nairobi Kenya Agricultural Research Institute Nat'l Veterinary Research Centre, Kikuyu
Poland	National Veterinary Research Institute Pulawy
Portugal	Laboratorio Nacional de Veterinaria Lisbon
Republic of South Africa	Onderstepoort Institute for Exotic Diseases Onderstepoort Veterinary Institute Onderstepoort
Russia	All-Russian Research Institute for Animal Health Vladimir
Spain	Centro de Investigacion en Sanidad Animal Valdeolmos 28130 Madrid Laboratorio de Sanidad y Produccion Animalde Madrid 28110 Algete, Madrid
United Kingdom	Institute for Animal Health, Pirbright Laboratory Working Surrey, CVL Weybridge, Addlestone Surrey

**FIGURE 3-8-1 List of Laboratories Working with Exotic Viruses, Including FMD**

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## Organisms and Vectors

Organisms are living cultures or collections of animals or their derivatives which may introduce or disseminate any contagious or infectious disease of animals, including poultry. Importations regulated as organisms include the following:

- ◆ Bacterial cultures
- ◆ Culture medium
- ◆ Excretions
- ◆ Fungi (including yeast)
- ◆ Ticks, mites, sand flies, mosquitoes
- ◆ Tissues of livestock and birds
- ◆ Viruses

A vector can be an animal, an insect, or an organism that: (1) has been exposed to or inoculated with any contagious, infectious, or communicable disease agent of livestock or poultry; and (2) is capable of transmitting this agent to livestock or poultry.

**EXAMPLE**

Examples of animals that can serve as vectors include chickens and other avian species, ferrets, horses, ruminants (cattle, sheep, goats), or swine.

Examples of insects that can serve as vectors include ticks, mites, sand flies, and mosquitoes.

Refer live animals, excluding laboratory animals, to the nearest VS office. Refer arthropods that can serve as vectors to VS, TTSPS.

When a VS permit **does not** authorize entry to the importation of organisms or vectors, use [Table 3-8-12](#) which directs you to the final regulatory action to take.



**TABLE 3-8-12 Regulatory Action to Take on Organisms and Vectors**

If the importation is for:	And the product is:	Then:
Research or biological use	Veterinary biologic used for the diagnosis, treatment, or prevention of animal diseases including bacterins and vaccines	<ol style="list-style-type: none"> <li>1. <b>DO NOT RELEASE</b> the HOLD</li> <li>2. ADVISE the importer of the HOLD because the importation requires a VS permit authorizing its entry</li> <li>3. PROVIDE the importer with the appropriate options, including applying for a veterinary biological product permit issued by VS, CVB (see <a href="#">page 2-4-27</a>)</li> </ol>
	Other than a veterinary biologic	GO to <a href="#">Table 3-8-13</a>
Pharmaceutical use	Bulk shipment to be used as drugs, medicine, nutritional supplements, or in test kits	<ol style="list-style-type: none"> <li>1. <b>DO NOT RELEASE</b> the HOLD</li> <li>2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing its entry</li> <li>3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-27</a>)</li> </ol>
	In final dosage form	GO to <a href="#">Human Pharmaceuticals and Human Vaccines</a> on <a href="#">page 3-15-12</a>

### Organisms and Vectors for Research or Biological Use

Organisms and vectors may be imported for scientific studies. They include such materials as microorganisms (bacteria, viruses, fungi), sera, cell lines and their products, antitoxins, and proteins such as hormones and enzymes. They are used to diagnose, treat, or prevent human and animal diseases.

Some examples of organisms and vectors which are regulated for research or biological use follow:

- ◆ Antitoxins and antivenoms
- ◆ Ascitic fluid from mouse or rat
- ◆ Cell and tissue cultures
- ◆ Cell line
- ◆ Culture media
- ◆ Enzymes
- ◆ Hybridoma cells
- ◆ Microorganisms (bacteria, fungi, protozoans, and viruses)
- ◆ Monoclonal antibodies
- ◆ Reagents

## ◆ Tissue samples



Some biological products are highly perishable. Therefore, expedite an importation when you are authorized to release the importation. If you **cannot** release the HOLD, then allow the importer to apply dry ice or refrigerate the by-product.

When a VS permit **does not** authorize entry to the importation of organisms or vectors, use [Table 3-8-13](#) that directs you to the final regulatory action to take.

**TABLE 3-8-13 Where to Find Regulatory Action on Organisms and Vectors Imported for Research or Biological Use**

If the importation is:	Then:
Amphibians, fish, reptiles, shellfish	GO to <a href="#">Table 3-8-11</a>
Canines (dogs) or felines (cats)	GO to <a href="#">Table 3-8-10</a>
Cell and tissue cultures, hybridoma cells, recombinant and nonrecombinant cell lines, and their products	GO to <a href="#">Table 3-8-14</a>
Live laboratory animals	GO to <a href="#">Table 3-8-7</a>
Microorganisms (bacteria, fungi, protozoans, and viruses)	GO to <a href="#">Table 3-8-4</a>
Monoclonal antibodies, ascitic fluid, and tissue culture supernatants	GO to <a href="#">Table 3-8-16</a>
Test kits and kit components	GO to <a href="#">Table 3-8-17</a>
Organisms and vectors <b>not</b> listed above	1. <b>DO NOT</b> RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

### Hybridoma Cells, Recombinant and Nonrecombinant Cell Lines, Cell and Tissue Cultures, and Their Products

Recombinant cell lines are those which have foreign genetic material inserted into their genetic material. The purpose is to produce many copies of a specific product, such as a human viral gene, in a system which is capable of replicating rapidly or expressing a desired protein. Some examples of cell lines which are often recombinant are NSO, Chinese hamster ovary (CHO), human stromal cell line containing genes for SV40, and mouse embryonic stem cell line transfected with human 2 virus gene.

Nonrecombinant cell lines have **not** had their genetic material manipulated. Many of the recombinant cell lines can also be nonrecombinant. CHO, NSO, COS-1, *Spodoptera frugiperda* (SF9), and mouse embryonic stem cells (HM1) are sometimes non-recombinant.



Some biological products are highly perishable. Therefore, expedite an importation when you are authorized to release the importation. If you **cannot** release the hold, allow the importer to apply dry ice or refrigerate the by-product.


When a VS permit **does not** authorize entry to the importation the following products, then use [Table 3-8-14](#) that directs you to the final regulatory action to take:

- ◆ Ascitic fluid
- ◆ Cell and tissue cultures
- ◆ Cell lines
- ◆ Hybridoma cells
- ◆ Monoclonal antibodies
- ◆ Tissue culture supernatant

**TABLE 3-8-14 Hybridoma Cells, Recombinant and Nonrecombinant Cell Lines, Cell and Tissue Cultures, and Their Products**

If the importation is:	And is of:	And is for:	Then:
Cell lines	<ul style="list-style-type: none"> <li>◆ Avian origin</li> <li>◆ Equine origin</li> <li>◆ Ruminant origin</li> <li>◆ Swine origin</li> </ul>	In vivo use <b>or</b> in vitro use	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing its entry</li> <li>3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-27</a>)</li> </ol>
<ul style="list-style-type: none"> <li>◆ Hybridomas</li> <li>◆ Recombinant cell lines</li> <li>◆ Nonrecombinant cell lines</li> <li>◆ Rodent cell lines</li> </ul>	<b>Other than</b> avian, equine, ruminant, or swine origin	→	GO to <a href="#">Table 3-8-15</a>
<ul style="list-style-type: none"> <li>◆ Ascitic fluids</li> <li>◆ Monoclonal antibodies</li> <li>◆ Tissue culture supernatants</li> </ul>	<b>Other than</b> avian, equine, ruminant, or swine origin	→	GO to <a href="#">Table 3-8-16</a>

**TABLE 3-8-15 Hybridoma, Recombinant and Nonrecombinant Cell Lines, and Rodent Cell Lines Not of Avian or Livestock Origin**


If:	And is of:	And is for:	And:	Then:
<ul style="list-style-type: none"> <li>◆ Hybridoma</li> <li>◆ Recombinant cell lines</li> <li>◆ Nonrecombinant cell lines</li> <li>◆ Rodent cell lines</li> </ul>	Other than avian origin or livestock origin	In vivo use		1. <b>DO NOT</b> RELEASE the HOLD 2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-27</a> )
		In vitro use	Is accompanied by the proper certification <sup>1</sup>	RELEASE
			Lacks the required certification	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required statement(s)

1 An **original** written declaration and signed statements on the producer's or shipper's letterhead that states and affirms in a clear and concise manner, the following information:

- ◆ Identifies the materials as a cell line or product of a cell line
- ◆ States that the material is for in-vitro use or in-vivo use in humans
- ◆ States that the material **did not** originate from a facility where work with exotic viruses affecting livestock and avian species is conducted
- ◆ States that the material is **not** recombinant, **or** if recombinant, contains **no** genes and expresses **no** products of exotic livestock or poultry disease agents

## Monoclonal Antibodies, Ascitic Fluid, and Tissue Culture Supernatants

TABLE 3-8-16 Monoclonal Antibodies, Ascitic Fluid, Tissue Culture Supernatants

If:	And:	And:	Then:
<ul style="list-style-type: none"> <li>◆ Ascitic fluid</li> <li>◆ Monoclonal antibodies</li> <li>◆ Tissue culture supernatants</li> </ul>	<ul style="list-style-type: none"> <li>◆ In vitro use</li> <li>◆ In vivo use in humans</li> </ul>	Is accompanied by the producer's or shipper's declaration <sup>1</sup>	RELEASE
		Lacks the producer's/shipper's declaration	<b>DO NOT RELEASE</b> the HOLD until the importer provides the required statement
	Not for use in humans		1. <b>DO NOT RELEASE</b> the HOLD 2. ADVISE the importer of the hold because the importation may require a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-27</a> )

1 An **original** written declaration and signed statements on producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:

- ◆ Identifies the material as a monoclonal antibody
- ◆ Identifies the name of the immunogen
- ◆ States the antibodies are for in vitro use, or if applicable, in vivo use in humans
- ◆ States that the material **did not** originate from a facility where work with exotic viruses affecting livestock and avian species is conducted
- ◆ States that the material is **not** recombinant, or if recombinant, states that the material contains **no** genes and expresses **no** products of exotic livestock or poultry disease agents

## Reagents

Reagents are used to detect the presence of substances by the chemical reactions or biological activity they cause. Reagents may be of animal origin or chemically synthesized and are usually imported for biological use. Reagents of animal origin can be regulated under different animal by-products. Some of these are monoclonal antibodies, bovine serum albumin, ruminant and porcine enzymes, collagen, heparin, rabbit antibodies, and cholesterol. When a VS permit **does not** authorize entry to the importation of the reagent, use the index to find the specific reagent and see that page.

## Test Kits and Kit Components




Test kits manufactured to diagnose human conditions (e.g., diseases, metabolic imbalances, pregnancy, etc.) or for general laboratory uses unrelated to the diagnosis of human conditions (e.g., DNA sequencing) **do not** require a VS permit, regardless of any animal-derived component in the kits. These test kits **must** be prepackaged, labeled, and ready for use.

Individual kit components that are packaged for final use (e.g., vials of bovine enzyme, goat antiserum, albumin) **do not** require a VS permit.

What does require a VS permit are animal-derived kit components that are imported in bulk (e.g., drum of powdered bovine enzyme) and are **not** packaged for final use.

Test kits which are manufactured to diagnose animal diseases require APHIS Form 2006, United States Veterinary Biological Product Permit. This permit is issued by the Center of Veterinary Biologics. See [\*\*Processing Importations Authorized Entry by a VS Permit\*\*](#) on page 2-4-31 for processing animal products and by-products imported under permit. See [\*\*Table 3-8-17\*\*](#) that directs you to the final regulatory action to take.

TABLE 3-8-17 Test Kits and Kit Components

If:	And is:	And is for:	And the importation:	Then:
<ul style="list-style-type: none"> <li>◆ Test kits</li> <li>◆ Test kit components</li> </ul>		◆ Diagnosis of human conditions	Is accompanied by the producer's or shipper's declaration <sup>1</sup>	RELEASE
		◆ General laboratory uses <b>unrelated</b> to the diagnosis of human conditions	<b>Lacks</b> the shipper's/producer's declaration or statements <sup>1</sup>	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required statement
		◆ Diagnosis of animal diseases		<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer of the hold because the importation requires a VS permit authorizing its entry</li> <li>3. PROVIDE the importer with the appropriate options including applying for a veterinary biological product permit issued by VS, CVB (see <a href="#">page 2-4-27</a>)</li> </ol>
	Animal-derived, in bulk, and <b>not</b> packaged for final use		Is covered by an applicable guideline  Is <b>not</b> covered by an applicable guideline	FOLLOW the applicable guidelines  <ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer of the hold because the importation may require a VS permit authorizing its entry</li> <li>3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-27</a>)</li> </ol>

1 An **original** written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:

- ◆ Test kits and/or kit components are **not** intended to diagnose infectious animal diseases
- ◆ Test kits and/or kit components are prepackaged and ready for use

## Semen, Ova, and Embryos

Semen is live animal sperm. Ova are live animal eggs. Embryos are live, fertilized eggs. Semen, ova, and embryos are imported either for reproductive (i.e. breeding), or research purposes.



Some biological products are highly perishable. Therefore, expedite an importation when you are authorized to release the importation. If you **cannot** release the hold, allow the importer to apply dry ice or refrigerate the by-product.

When a VS permit **does not** authorize entry for the importation of equine semen, use [Table 3-8-18](#); for semen other than from equine, use [Table 3-8-19](#); and for ova, or embryos, use [Table 3-8-20](#) which directs you to the final regulatory action to take.



## Semen Originating from Canada

TABLE 3-8-18 Semen Originating from Canada











If the country of origin is:	And the semen is:	And the semen is imported for:	And is presented at:	And:	Then:
Canada	Equine <sup>1</sup>			Origin and species can be confirmed <sup>2</sup>	RELEASE
				Origin and species <b>cannot</b> be confirmed	REFER the shipment to the VS Port Veterinarian
	<ul style="list-style-type: none"> <li>◆ Ruminants, <b>other than</b> sheep and goats</li> <li>◆ Poultry</li> <li>◆ Swine</li> </ul>	Reproduction <sup>3</sup>	Canadian land border port designated for this import <sup>4</sup>		REFER the shipment to the VS Port Veterinarian
			Port cited in 9CFR§98.33(a) or §98.33(d)	Is accompanied by a VS permit (VS Form 17-135)	1. CONTROL as specified on the permit 2. REFER the shipment to the VS Port Veterinarian
				<b>Lacks</b> a VS permit (VS Form 17-135)	REFUSE ENTRY
	Ruminants, sheep and goats <b>only</b>	Reproduction <sup>3</sup>		Is accompanied by a VS permit (VS Form 17-135)	1. CONTROL as specified on the permit 2. REFER the shipment to the VS Port Veterinarian
				<b>Lacks</b> a VS permit (VS Form 17-135)	REFUSE ENTRY

TABLE 3-8-18 Semen Originating from Canada (continued)

If the country of origin is:	And the semen is:	And the semen is imported for:	And is presented at:	And:	Then:
Canada	<ul style="list-style-type: none"> <li>◆ Ruminants, including sheep and goats</li> <li>◆ Poultry</li> <li>◆ Swine</li> </ul>	Diagnosis or research (in vitro use <b>only</b> )		Is accompanied by a VS permit (VS Form 16-6A)	RELEASE or CONTROL as specified on the permit
				<b>Lacks</b> a VS permit (VS Form 16-6A)	REFUSE ENTRY
	Dogs <sup>5</sup>	Reproduction <sup>6</sup>		Origin and species can be confirmed <sup>2</sup>	RELEASE
				Origin and species <b>cannot</b> be confirmed	REFER the shipment to the VS Port Veterinarian
		Diagnosis or research			GO to <a href="#">Table 3-8-10</a> on page 3-8-13
	Bees			Is accompanied by a CFIA certificate verifying Canadian origin	RELEASE
				<b>Lacks</b> the appropriate CFIA certificate	REFUSE ENTRY
	Animal <b>other than</b> listed above				<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer that the importation may require a VS permit authorizing entry</li> <li>3. HAVE the importer contact VS, TTSPS (see <a href="#">page 2-4-27</a>)</li> </ol>

1 Equine includes animals like asses, burros, donkeys, horses, or zebras.

2 Outside labeling indicating species and origin is acceptable.

3 Consider semen for reproduction to be a live animal importation regulated by VS.








4 Canadian border ports are listed in 9CFR§98.33(b).

5 You **must** be able to confirm that the semen is dog semen.

6 If dog semen is to be used for reproductive purposes and **not** research, then the semen is unrestricted as long as the species is confirmed.

## Semen Originating from Countries Other Than Canada

**TABLE 3-8-19 Semen from Countries Other Than Canada**

If the country of origin is:	And the semen is from:	And is imported for:	And is from:	And:	Then:
Other than Canada	<ul style="list-style-type: none"> <li>◆ Equine<sup>1</sup></li> <li>◆ Poultry</li> <li>◆ Ruminants</li> <li>◆ Swine</li> </ul>	Reproduction <sup>2</sup>		Is accompanied by a VS permit (VS Form 17-135)	1. CONTROL as specified on the permit 2. REFER the shipment to the VS Port Veterinarian
				Lacks a VS permit (VS Form 17-135)	REFUSE ENTRY
		Diagnosis or research (in vitro use <b>only</b> )		Is accompanied by a VS permit (VS Form 16-6A)	RELEASE or CONTROL as specified on the permit
				Lacks a VS permit (VS Form 16-6A)	REFUSE ENTRY
	◆ Dogs <sup>3</sup>	Reproduction <sup>4</sup>		Species can be confirmed <sup>3</sup>	RELEASE
				Species <b>cannot</b> be confirmed <sup>3</sup>	REFER the shipment to the VS Port Veterinarian
		Diagnosis or research			GO to <a href="#">Table 3-8-10</a> on <a href="#">page 3-8-13</a>
	Bees		Australia, Bermuda, Canada, France, Great Britain, or Sweden	Is accompanied by a government certificate verifying the country of origin	RELEASE
				Lacks the appropriate certificate	REFUSE ENTRY
			Country <b>other than</b> listed above		REFUSE ENTRY
	Animal <b>other than</b> listed above				1. <b>DO NOT</b> RELEASE the HOLD 2. ADVISE the importer that the importation may require a VS permit authorizing its entry 3. HAVE the importer contact VS, TTSPS (see <a href="#">page 2-4-27</a> )

1 Equine includes animals like asses, burros, donkeys, horses, or zebras.











2 Consider semen for reproduction to be a live animal importation regulated by VS.

3 You **must** be able to confirm that the semen is dog semen. Outside labeling indicating species and origin is acceptable.

4 If dog semen is to be used for reproductive purposes and **not** research, then the semen is unrestricted as long as the species is confirmed.

## Embryos and Ova

TABLE 3-8-20 Embryos and Ova

If:	And harvested from:	And is imported for:	And:	And the importation:		
Embryos or ova <sup>1</sup>	◆ Equine <sup>2</sup> ◆ Ruminants ◆ Swine	Reproduction <sup>3</sup>		Is accompanied by a VS permit (VS Form 17-135)	1. CONTROL as specified on the permit 2. REFER the shipment to the VS Port Veterinarian	
				Lacks a VS permit (VS Form 17-135)	REFUSE ENTRY	
		Diagnosis or research		Is accompanied by a VS permit (VS Form 16-6A)	RELEASE or CONTROL as specified on the permit	
				Lacks a VS-issued permit (VS Form 16-6A)	REFUSE ENTRY	
	Bees		From Australia, Bermuda, Canada, Great Britain, or Sweden	Is accompanied by a government certificate verifying the country of origin	RELEASE or CONTROL as specified on the permit	
			From <b>other than</b> a country listed above		Lacks the appropriate certificate	REFUSE ENTRY
					REFUSE ENTRY	
	Insects		Labeled with PPQ Form 599		RELEASE	
			Not labeled with PPQ Form 599		REFUSE ENTRY	
	Mosquitoes			Is accompanied by a VS permit (VS Form 16-6A)	RELEASE or CONTROL as specified on the permit	
				Lacks a VS permit (VS Form 16-6A)	REFUSE ENTRY	
	Animal <b>other</b> than listed in the cells above				1. <b>DO NOT</b> RELEASE the HOLD 2. ADVISE the importer that the importation may require a VS permit authorizing its entry 3. HAVE the importer contact VS, TTSPS (see <a href="#">page 2-4-27</a> )	

1 Used, empty embryo or ova containers are regulated under [Empty Semen and Embryo Containers](#) on page 2-2-12.

2 Equine includes animals like asses, burros, donkeys, horses, or zebras.

3 Consider semen for reproduction to be a live animal importation regulated by VS.